Basic Building Block Profile

Building Block: Patient Recruitment & Enrollment

Vision

The Vision is based on 3 pillars:
1) Diabetes Carousel:
Is an online public platform to share information about diabetes, diabtes treatment, QoL, R&D processes and clinical trials for diabetes patients with patients and the wider public interested in diabetes. Website enables peer-to-peer interaction/communication between platform users to increase overall value and time spent on portal. Patients interested in joining RDCT will be informed about and invited to the
2) My Patient/My Participant Portal:
Is an online platform hosting the landing page for patient digital pre-screening, digital recruitment and patient consenting into the RDCT. Through integration/intercation with EDC,eICF, tele-health, IRT/IWRS functionalities patients will be screened, consented recruited, treated and provided with study drug in both, remote and conventional arm.
3) Patient Recruitment Campaigns: digital and conventional

Included activities in the RFP

The following activities are included in the RFP:

- **Intelligent, interactive online platform** (cloudbased) to host public information on diabetes
- **Peer-to-peer (patient-to-patient) Network**
- **Ability to integrate App Solutions** to ensure (depending on drug used) / ability to integrate data from smart cap devices tracking drug intake
- **Calendar integration** to patients calendars / email inbox
- **Patient Recruitment Service Provider** capable of both digital and non-digital Patient Recruitment specialized for diabetes/metabolic disorders.
  Core competencies:
  Interaction with diabetes patient communities, patient organisations, influencer outreach, providing access to MHR/EHR data; comfortable to use of Algorithms/AI to pre-identify patients through aggregated data/digital footprint (data purchasing diabetes books/accessories via Amazon and others Vendors interacting with pharmacies for information on prescribed diabetes drugs), SEO capabilities.

The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

Excluded activities from the RFP

The activities below are already covered by internal partners and **excluded from the RFP**:

- Differentiated access, functionality and content for patients, sponsor, CRO, investigator and site staff
- Storage and Tracking of patient, site/investigator trainings and training materials
- Patient engagement messaging as push out notifications
- Distribution of study/IP-related patient information based on treatment arm (starter pack)
- KPI/Metric tracking for use of Portal
- eICF/ePRO functionality built into platform, video storage, information sharing and storage/ all ICF material needs to be stored/be available at all times during the study (for video)

RFP – Knockout Criteria

For the activities included in the RFP we have identified a number of knockout criteria that will exclude the technology vendor in the case that one or more of them are not met.

Peer-to-peer (patient-to-patient) Network

The technology will be rejected if:

1. not GDPR compliant
2. does not allow for Member Password and Login Identity
3. does not provide membership eligibility check

Ability to integrate App Solutions to ensure (depending on drug used) / ability to integrate data from smart cap devices tracking drug intake

The technology will be rejected if:

1. is not compatible for IMP used in PILOT

Calendar integration to patients calendars / email inbox

The technology will be rejected if:

1. unable to integrate into iOS and Android and all current digital calendars
2. unable to run on all current mobile as well as stationery devices

Patient Recruitment Service Provider capable of both digital and non-digital Patient Recruitment specialized for diabetes/metabolic disorders

The technology will be rejected if:

1. no previous experience/expertise in metabolic/diabetes (2 clinical trials)
2. unable to demonstrate experience in a) digital
   b) conventional recruitment (at least 2 trials in relevant TA)
3. unable to demonstrate experience/solutions for Behavioral Targeting/Retargeting, SEO, interaction with PAGs, influencers, POLs

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4. no P4P (pay for randomization)

Intelligent, interactive online platform (cloudbased) to host public information on diabetes research, treatment, therapy i.e. / providing link to clintrial.gov/pubmed etc.

The technology will be rejected if:

1. not GDPR-compliant
2. no integration with CTIS
3. no interface to variety of external online platforms/systems

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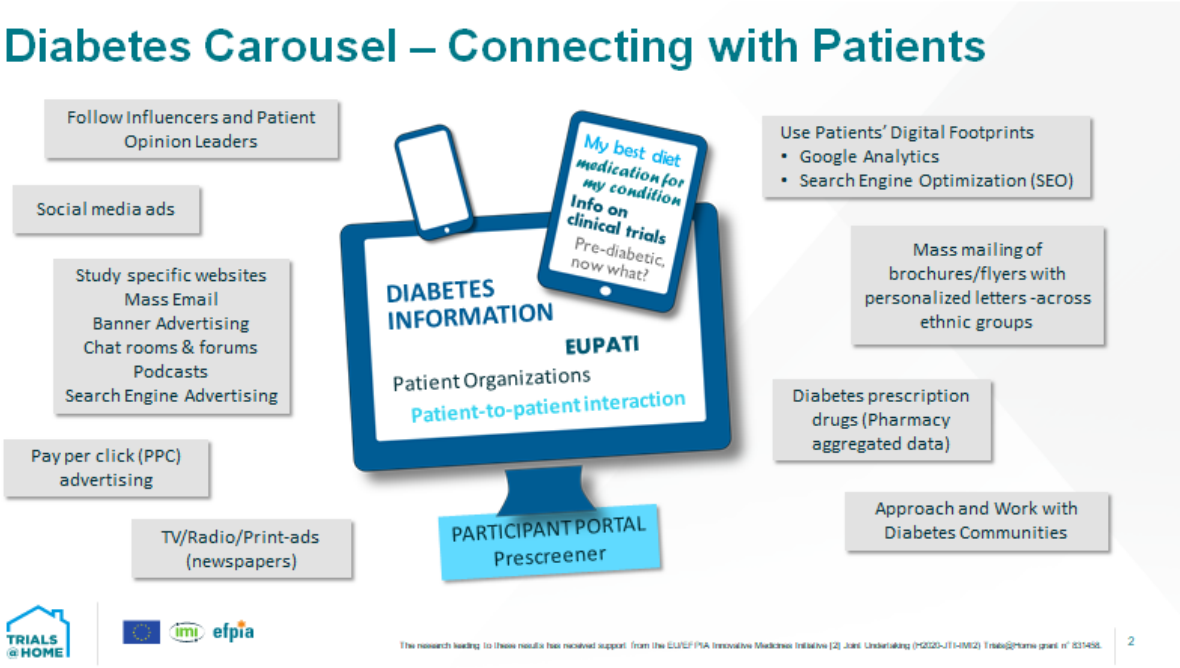
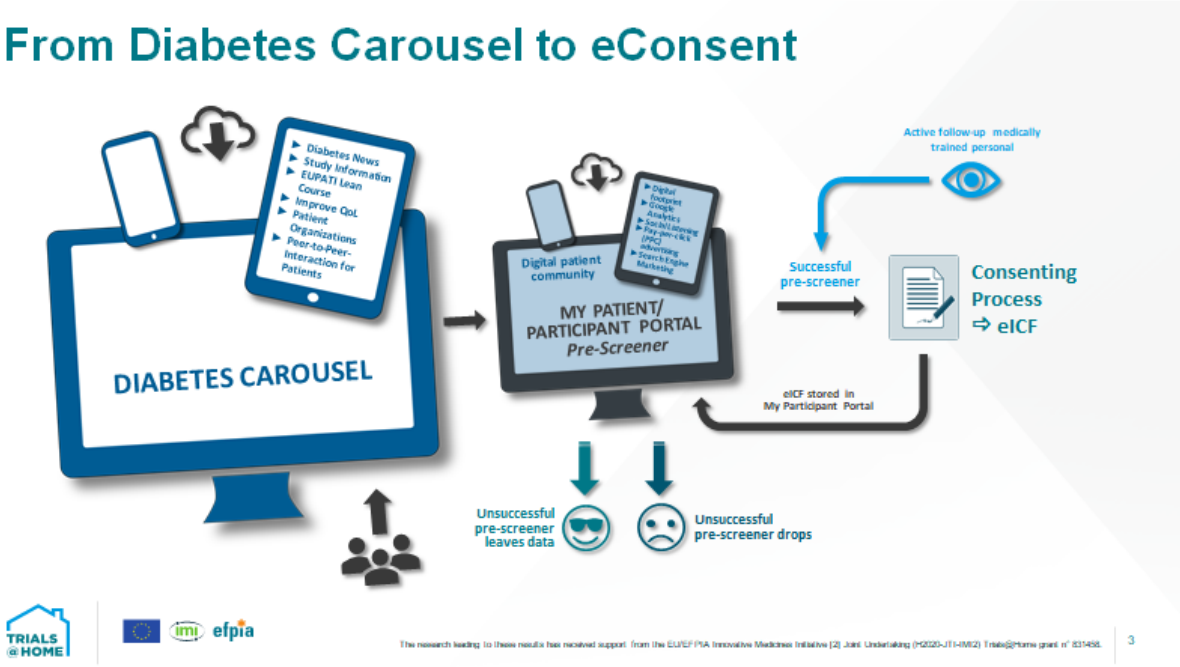
Graphs





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